REMARKS

Status of the Claims

Claims 1-27 remain pending.

Claim objection

As a preliminary matter, it is noted that claim 10 was labeled as "currently amended" rather than "original," in the response to the Office Action of May 3, 2004, due to the removal of an extraneous comma in the last line of the claim.

Claim rejection under 35 U.S.C. §112, second paragraph

Claims 14 and 16 are rejected under 35 U.S.C. §112, second paragraph. These rejections are believed to be moot in view of the claim amendments presented above, which are along the lines suggested in the Office Action. No change in claim scope is intended or effected by these amendments.

Rejection of claims 1-27 under 35 U.S.C. §102(b) and 103(a)

Claims 1-10, 13, 15, 18, 20-22, 25 and 27 continue to be rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,824,049 (Ragheb).

Claims 1, 5-10, 12, 13 and 14 continue to be rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,725,567 (Wolff).

Claims 2 and 11 continue to be rejected under 35 U.S.C. §103(a) as being unpatentable over Wolff in view of U.S. Patent No. 5,630,840 (Mayer).

Claims 14, 16, 17, 19, 23, 24 and 26 continue to be rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb in view of Wolff.

These rejections and their supporting remarks are respectfully traversed.

As previously noted, claim 1 is directed to an intraluminal stent, which comprises (a) a metallic reinforcing component and (b) a biodegradable polymeric material covering at least a portion of the metallic reinforcing component. The metallic reinforcing

component in the stent provides structural reinforcement for the stent. However, the metallic reinforcing component is insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

As noted in paragraph [0031] of the present specification, the composite intraluminal stent of the claimed invention, in contrast with known composite stents, utilizes both the metallic component and the biodegradable polymeric component to provide the mechanical properties necessary for maintaining the patency of the lumen upon implantation of the stent into a body lumen. Whereas known composite stents employ a biodegradable polymeric component as a coating, for example, for incorporating and providing localized release therefrom of a therapeutic agent, such a coating layer does not provide the stent with mechanical strength necessary for maintaining luminal patency upon implantation. This task is left to the metallic component.

Moreover, and as indicated in paragraph [0034] of the present specification, the composite intraluminal stent of the present invention provides distinct advantages relative to composite stents in which the biodegradable polymeric component does not substantially contribute to the mechanical strength of the stent. For example, because the metallic reinforcing component is not relied on as the sole source of mechanical strength, a stent can be provided that advantageously utilizes less metal. Metallic materials are often more rigid and less biocompatible than biodegradable polymeric materials. For instance, the relative rigidity of metallic materials can compromise the goal of providing a stent that is biomechanically compatible, i.e., compliant with the contacting lumen walls. Because less metal is utilized in a stent in accordance with the present invention, the metallic component of the stent can be constructed from thinner and more flexible metallic filaments or sheets to provide a flexible metallic reinforcing component. Upon in vivo biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be advantageously less bulky and have a smaller surface area in direct contact with the lumen walls. At such point, the remaining flexible metallic framework of the stent will be more compliant with the contacting lumen walls and be less likely to cause damage or injury to the same if left implanted indefinitely.

By appropriate selection of metallic and biodegradable polymeric materials, the present invention provides an enhanced ability to customize the mechanical properties of an intraluminal stent based, for example, on the time-dependent changes associated with lumen healing or remodeling. The present invention thus relies on the desirable properties of both metallic and biodegradable polymeric materials to provide a composite biomechanically compatible stent. See paragraph [0036] of the present specification.

As explained in response to the prior Office Action of May 3, 2004, such a stent is neither taught nor suggested by Ragheb, Wolff and Mayer, either alone or in combination.

In response, the Office urges the following (emphasis added): "Whether a metallic structure can maintain patency of a lumen depends on many factors, including the lumen into which it is implanted. Therefore, *any* prior art stent is capable of being insufficient to maintain patency of a lumen without a polymeric cover....The Ragheb and Wolff stents meet the structural requirements of the claims, as they have a metallic component and a biodegradable polymeric cover."

Applicant disagrees.

In a rejection based on inherency, an Examiner must provide factual and technical grounds establishing that the inherent feature *necessarily* flows from the teachings of the prior art. *See Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *see also In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (holding that inherency must flow as a necessary conclusion from the prior art, not simply a possible one).

Even assuming solely for the sake of argument that it is theoretically possible that a prior art stent *might* exist whose metallic components are insufficient to maintain the patency of a lumen without the aid of a polymeric covering (e.g., where the stent is for some reason inserted into a lumen that it is not designed to occupy), this by no means *necessarily* flows from the prior art. Indeed, as indicated in paragraph [0031] of the present specification, known composite stents employ a biodegradable polymeric component as a coating, for instance, for purposes providing a therapeutic agent (see, e.g., Wolff), rather than for purposes of providing the stent with mechanical strength

sufficient for maintaining luminal patency upon implantation, which task is left to the metallic component.

With respect to the Office's remarkably far-reaching assertion that *any* prior art stent is capable of being insufficient to maintain patency of a lumen without a polymeric cover, the validity of this statement is questioned (for example, it is not seen why the stents of the prior art would not be able to maintain the patency of any and all body lumens), and the Office is requested to provide factual and technical grounds establishing that this is necessarily the case.

For at least these reasons, it is respectfully submitted that claim 1, as well as claims 2-27 depending therefrom, are patentable over Ragheb, Wolff, and Mayer.

Accordingly, reconsideration and withdrawal of the prior art rejections of claims 1-27 are respectfully requested.

CONCLUSION

Applicants submit all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

FEES

The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

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Respectfully submitted,

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I hereby certify that this document and any document referenced herein are being sent to the United States Patent and Trademark office via Facsimile to: 703-872-9303 on Nov. 23, 2004.

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